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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,910

06/10/2008

Steven A. Boyd

GEN/034

6041

7590

05/18/2010

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EXAMINER

ZAREK, PAUL E

ART UNIT

PAPER NUMBER

1628

MAIL DATE

DELIVERY MODE

05/18/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/593,910	<b>Applicant(s)</b> BOYD ET AL.	
	<b>Examiner</b> Paul Zarek	<b>Art Unit</b> 1628	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 February 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5,7,9-17 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,7,9-17 and 28-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/15/2008</u> .  | 6) <input type="checkbox"/> Other: _____                          |

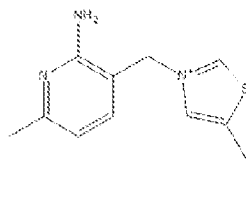
## DETAILED ACTION

### *Status of the Claims*

1. Claims 1-3, 5, 7, and 9-17 have been amended, Claims 28-30 have been added, and Claims 8 and 18-27 have been cancelled by the Applicant in correspondence filed on 02/16/2010. Claims 1-3, 5, 7, 9-17, and 28-30 are currently pending. This is the first Office Action on the merits of the claim(s).

### *Election/Restrictions*

2. Applicant's election with traverse of Group I, drawn to a compound of formula I where in none of  $R^1$ ,  $R^2$ ,  $R^3$ , and  $R^4$  contain cyclic groups,  $R^5$  and  $R^6$  are -H,  $R^7$  and  $R^8$  are -H, alkyl, or haloalkyl,  $R^9$  does not contain a cyclic group, antibody, polysaccharide, or peptide,  $R^a$  and  $R^b$  are



-H or -OH, and  $R^c$  and  $R^d$  are -H, and the species in the reply filed on 02/16/2010 is acknowledged. The traversal is on the ground(s) that all of the instant claims have a common nucleus and that the number and type of substituents on that common nucleus is irrelevant to unity of invention. Applicants also contend that it would not constitute an undue search burden to search the entirety of the claims. This is not found persuasive because Applicants' amendment to the claims has cancelled subject matter that is not encompassed by the elected Group I. Examiner notes that the nucleus is anticipated by the prior art (see below), thus the invention as claimed does not possess a special technical feature over the prior art.

Art Unit: 1628

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1-3, 5, 7, 9-17, and 28-30 read on the elected group and species and are examined herein.

### ***Priority***

4. Applicant's claim for the benefit of a prior-filed International Application no. PCT/US05/09970 (filed on 03/23/2005) which claims the benefit prior-filed provisional application no. 60/556,217 (filed on 03/24/2004) under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. The effective filing date of the instant application is 03/24/2004.

### ***Claim Objections***

5. Claim 17 is objected to because of the following informalities: there is no space between "claim" and "16." Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112 (2<sup>nd</sup> paragraph)***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2, 3, 7, 10, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 limits R<sup>9</sup> to be either -OR<sup>10</sup> or NR<sup>11</sup>R<sup>12</sup>, which means that R<sup>10</sup> and R<sup>12</sup> can not coexist on the same molecule. Claims 2, 3, 7, 10, and 11 depend from Claim 1 and contain the limitation "the compound of claim 1 . . . wherein R<sup>10</sup> is . . . and R<sup>12</sup>

Art Unit: 1628

is . . .” (emphasis added), which means that a molecule of Claim 1 contains both R<sup>10</sup> and R<sup>12</sup>.

Thus, Claims 2, 3, 7, 10, and 11 lack antecedent basis for a molecule that contains both R<sup>10</sup> and R<sup>12</sup>. Applicants can overcome this rejection by amending Claims 2, 3, 7, 10, and 11 to change from “R<sup>10</sup> is . . . and R<sup>12</sup> is . . .” to “R<sup>10</sup> is . . . or R<sup>12</sup> is . . .”.

8. Claims 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 16 contains the limitation of “a compound of claims 1-15,” which encompasses cancelled claims. Claims can not depend from cancelled claims. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

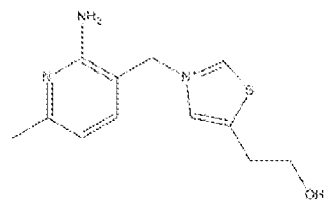
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-3, 5, 7, 9-16, and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Ostrovskii, et al. (Bioorganicheskaya Khimiya, 1977).

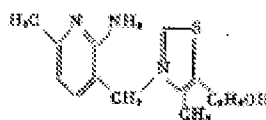
11. Claim 1 of the instant application is drawn to a compound of formula I. Claims 2, 3, 5, 7, 9-15, and 28-30 limit the various substituents of formula I. Claim 16 is drawn to a

Art Unit: 1628

pharmaceutical composition comprising a compound of formula I. The elected species,



, reads on Claims 1-3, 5, 7, 9-16, and 28-30.



12. Ostrovskii, et al., teach the compound, (3'-N-Пиридиновъй аналог, pg 1086, first compound). Ostrovskii, et al., disclose that the compound is in a solution containing: 1  $\mu\text{M}$  thiamine analog (1 мкмопъ тиамина или его аналога) (e.g. the elected species), 4  $\mu\text{M}$  ATP (4 мкмопъ ATP), 20  $\mu\text{M}$   $\text{MgCl}_2$ , (20 мкмопъ  $\text{MgCl}_2$ ), and 20  $\mu\text{M}$  Tris-HCl (20 мкмопъ Трис-HCl-буфера) (pg 1088 para 3, lines 7-8). This solution is pharmaceutically acceptable. Therefore, Ostrovskii, et al., anticipate all the limitations of the rejected claims.

### ***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

Art Unit: 1628

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ostrowskii, et al. (above) in view of Ulusakarya, et al. (American Journal of Hematology, 1999).

16. Claim 17 is drawn to the pharmaceutical composition of Claim 16 further comprising a chemotherapeutic agent, antiangiogenic agent, or an agent which modulates signaling associated with hypoxic conditions in a cell.

17. Ostrowskii, et al., was described above. Briefly, Ostrowskii, et al., teach a pharmaceutical composition comprising the elected species (pg 1086, first compound; pg 1088 para 3, lines 7-8). Ostrowskii, et al., disclose that the compounds contained therein are thiamine analogs (Title) and that the elected species has properties similar to thiamine with respect to activating thiamin pyrophosphokinase (compare тиамин [pg 1084 first compound] with the 3’N-Пиридиновъй аналог, the elected species [pg 1086, first compound]). Thus, the elected species is considered an obvious variant of thiamine. Ostrowskii, et al., do not teach making a pharmaceutical composition further comprising an additional agent.

18. Ulusakarya, et al., teach that chemotherapy can lead to thiamine deficiency (Title). Administration of thiamine resulted in “dramatic clinical improvement” (pg 156, col 1, para 1, lines 5-6). Given that chemotherapy can lead to thiamine deficiency, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to administer thiamine, or a thiamine analog to treat the thiamine deficiency.

Art Unit: 1628

***Conclusion***

19. Claims 1-3, 5, 7, 9-17, and 28-30 are rejected.
20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/San-ming Hui/  
Primary Examiner, Art Unit 1628